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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,471	12/21/1999	VINCENT DIVINO, JR.	THOX:0021--1	3676

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THEROX, INC.
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IRVINE, CA 92612

EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/468,471

Applicant(s)

DIVINO, JR. ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-78 is/are pending in the application.
- 4a) Of the above claim(s) 56-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-50, 52-55 and 68-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-45, 47, 48, 52-55, 68, 69 & 75-77 stand rejected under 35 U.S.C. 102(b) as being anticipated by Love (3,142,296). Love discloses a liquid-to-liquid blood oxygenation assembly and method of use. The mixing chamber (1) has two inlets, (3) for the delivery of blood and (24) for the delivery of oxygen, and an outlet (30) for the oxygenated blood. The blood enters the chamber at point (4) and moves circularly or vortically to a pooling region. The interior of the chamber is pressurized. The gas dissolves in the blood thereby creating a gas-enriched fluid having a greater concentration of gas than the blood did originally. The inlet for the oxygen is perpendicular to that of the blood inlet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49, 50, 70-74 & 78 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Love ('296) in view of Grady (5,084,011). Love substantially discloses the invention as claimed, see explanation above, except for specifically teaching that the gas enriched fluid is hyperoxic, hyperbaric, and that the pressure the fluids are mixed at is greater than 760 mmHg.

Grady teaches of a system and method for oxygenating blood extracorporeally. The system includes a vessel, having a chamber for holding the fluids, for mixing a gas and a fluid under pressure. Grady teaches that the chamber may be maintained at about 4 atm pressure (i.e. 3040 mmHg), a pressure greater than 760 mmHg. With respect to claims 42-45, the supersaturated fluid used is oxygen gas, which inherently has a gas and a liquid phase, and oxygen is well known to be isotonic to blood. With respect to claims 48, 50, and 70-72, Grady teaches that the blood may be hyperbaric (greater than 760 mmHg) after being enriched with the supersaturated solution. (See entire disclosure including the figures) At the time of the invention, it would have been

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obvious to one having ordinary skill in the art to modify the method of Love to pressurize the chamber since it is well known that increased pressures increase the saturation level of the liquid.

Claim 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Love ('296) in view of Spears (5,693,017). Love substantially discloses the invention as claimed, see explanation above, except for using saline as the fluid that is supersaturated in the supersaturated fluid supply of the system and wherein the fluid is supersaturated under pressure within the mixing device.

Spears teaches of using saline as the fluid to be saturated with a gas in an apparatus and method for delivering supersaturated solutions to a delivery site. The supersaturated fluid supply is made in a vessel that is under pressure. The dissolving of oxygen or other gas under pressure ensures that no bubbles are in the fluid prior to delivery to the patient.

It would have been obvious to one having ordinary skill in the art to modify the system of Love such that saline is used as the fluid to be supersaturated with oxygen and that the saturation is done under pressure. The use of saline is well known in the art since saline is isotonic with blood. Dissolving a gas under pressure ensures that no bubbles are in the fluid prior to delivery to the patient to ensure that no embolism are formed.

Response to Arguments

Applicant's arguments filed 11/5/03 have been fully considered but they are not persuasive. Applicant's argues that the present invention is based upon an unexpected discovery of the inventors that the liquid-to-liquid gas diffusion for enriching a fluid with gas is rapid and efficient. Also, it was argued that the inventors further discover that the most effective and complete mixing of the two fluids is achieved when the fluid being enriched with the gas flows vortically in the mixing chamber. However, when taking the position that the invention is a result of greater than expected results, the issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2D 1091 231 USPQ 375 (Fed Circuit 1986). Further, the court has ruled that "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness....of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed Circuit 1985). See MPEP 716.02-.02(g). The presentation of attorney arguments are not sufficient to take the place of evidence. The burden is on the applicant to show evidence that the results are in fact unexpected and unobvious. Therefore, the position of the examiner that Love, by teaching a liquid-to-liquid mixing, will inherently achieve the liquid-to-liquid gas diffusion. Aside from any evidence supporting applicant's arguments, the rejections stand.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0873.


Patricia M Bianco
Primary Examiner
Art Unit 3762

January 8th, 2004